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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,700	01/14/2002	Colin Ratledge	401544	8613

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,700	RATLEDGE ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005 and 20 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,37-40,43-50,74,76,78,79,81 and 82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,37-40,43-50,74,76,78,79,81 and 82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RD

DETAILED ACTION

The amendment filed 3/1/05 and the supplemental amendment filed 4/20/05 are acknowledged. Claims 34, 37-40, 43-50, 74, 76, 78-79, 81 and 82 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47 and 81-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the cultivation of *C. cohnii* "in acetic acid and/or acetate ions".

No basis or support is found in the present specification for the productivity of *C. cohnii* recited in claims 81-82 comprising culturing *C. cohnii* in a "nutrient medium **containing** acetic acid and/or acetate ions, the acetic acid and/or acetate ions **comprising** the primary carbon source consumed by...".

Therefore, this material constitutes new matter and should be deleted.

Claims 34, 37-40, 43-50, 74, 76, 78-79, 81 and 82 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of acetic acid or acetate ions as the primary source is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Applicant's instant amendment to broaden to claims to "nutrient medium **containing** acetic acid and/or acetate ions, the acetic acid and/or acetate ions **comprising** the primary carbon source consumed by..." is not the invention as disclosed and argued throughout prosecution. The claims now of record are at least ambiguous as to whether acetic acid and/or acetate ions are or are not the primary carbon source in the method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, 37-40, 43-50, 74, 76, 78-79, 81 and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is confusing in the recitation "nutrient medium containing acetic acid and/or acetate ions, the acetic acid and/or acetate ions comprising the primary carbon source consumed by...". This recitation is at least ambiguous as to whether acetic acid or acetate ions are or are not the primary carbon source for the *Crypthecodinium cohnii* strain.

Claim 37 is vague indefinite and confusing in lacking proper antecedent basis in claim 34 for "as the primary carbon source".

Claim 47 lacks antecedent basis in claim 34 for culturing *C. cohnii* "in acetic acid and/or acetate ions". In claim 34 the cells are cultured in a nutrient medium.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vazhappilly *et al.* taken with Kyle and Du Preez *et al.*.

This rejection is applied to claim 34 to the extent that it is at least ambiguous whether acetic acid is the primary carbon source in the process.

Vazhappilly *et al.* discloses the cultivation of various microorganisms for the production of docosahexanoic acid (DHA) including *C. cohnii.* (See, e.g., Table 2). The microorganisms showed good heterotrophic growth when acetate was used as carbon source (Table 1 at p. 394).

The presence of other carbon sources will in principle not change this reasoning since the instant invention is directed to culturing in "nutrient medium **containing** acetic acid and/or acetate ions, the acetic acid and/or acetate ions **comprising** the primary carbon source consumed by...". Thus, the use of other carbon sources by the microorganism is not excluded from claim 34 and the amount of acetate used in the reference seems to indicate that it is the main, if not the sole, carbon source (see also p. 396, col. 2, paragraph 4). Since the nature of the carbon source will presumably not change drastically the metabolism at least of *C. cohnii*, it is assumed that during this culture DHA is produced. Applicant's attention is drawn to the fact that omission of features (explicit mention of production of DHA), does not mean that they are not (implicitly) present .

The reference differs from the claimed invention in that continuous culture is not used, as the absence of a stationary phase implies. However, Kyle *et al.* adequately demonstrate the production of DHA with a strain of *C. cohnii* wherein a carbon source was supplied continuously and the cells were harvested in the substantial absence of a stationary phase (See, e.g., Example.).

In addition, duPreez disclose the use of acetate as carbon source, independently of the kind of microorganism, wherein the pH is maintained substantially at a predetermined value (See, e.g., page 934, paragraph 4).

It is noted that acetic acid is a well known and cheaper alternative to glucose in fermentation cultures and the references Vazhappilly *et al.* and duPreez *et al.* adequately demonstrate that microorganisms grow well on acetate and that at least *C. cohnii* grows very well in acetate and would reasonably we expected to produce DHA successfully on this substrate when cultured in continuous culture in the absence of a stationary phase, as suggested by the teachings of Kyle, particularly whenever the "culturing process parameters" controlled are undefined.

The optimization of conditions identified as result-effective variables cited in the references, such as adjustment of concentration of substrates and pH for optimization of yield would have been prima facie obvious to a person having ordinary skill in the art, since the optimization of processes is the essence of biotechnical engineering..

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Vazhappilly *et al.* for the production of

DHA with microorganisms including *C. cohnii* by culturing in a "nutrient medium containing acetic acid and/or acetate ions, the acetic acid and/or acetate ions comprising the primary carbon source consumed by *C. cohnii* ...", as suggested by the teachings of Kyle and Du Preez *et al.* for the expected benefit of obtaining greater amounts of DHA by cultivation of microorganisms useful as a food supplement, especially in infant formula.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651